Remarks

This is in response to the final Office Action dated August 11, 2010 in the above-identified patent application.

I. Status of the Claims.

Claims 53-65, 67-71 and 76-80 were pending for purposes of the instant Office Action. Claim 53 was misidentified as "previously presented" although an amendment to that claim was made in the Reply dated June 11, 2010. This claim, as amended, is now correctly identified as "previously presented." Claims 1-52, 66, and 72-75 were previously canceled. Claim 80 was newly added in the previous Reply, and all inadvertent underlining has been removed. Accordingly, claims 53-65, 67-71 and 76-80, as amended, are now pending.

It is respectfully submitted that no new matter is presented by the above amendments. Reconsideration of the pending claims is respectfully requested.

II. Withdrawn Rejections

Applicants appreciate the withdrawal of the objection to claims 54-56 in view of the correction of the informalities.

Applicants further acknowledge the withdrawal of the rejection under 35 USC 112, second paragraph, of claims 56-66, 69-71, and 78-79 in view of the amendments to claims 56, 61, and 62 and cancellation of claim 66.

III. Current Grounds of Rejection

Claim Rejections – 35 USC §103

Claims 53-71 and 76-80 stand rejected under 35 USC §103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) in view of Ullman (US Pat. No. 4,215,104). This rejection is respectfully traversed.

Applicants respectfully submit that the cited references of Lieberman and Ullman describe tablets that are completely different than the tablets claimed in the subject invention. The tablets

of the subject invention overcome the well-known problem, recognized and acknowledged in Lieberman, of significant variation in drug dose following tablet splitting.

Breaking of the claimed tablets does not result in significant variation in the drug dose, a result which is due solely to the unique configuration of those tablets.

For example, the unexpected advantage exhibited by the tablet of claim 53 depends on its unique, layered configuration comprising (a) an active segment and (b) an inactive outer segment. The presence of the inactive outer segment allows the tablet to contain the deep score without affecting the integrity of the tablet during manufacture, shipping or storage. This unique inactive outer segment configuration, in combination with the deep score, facilitates breaking of the tablet and splitting of the dose *without significant variation in the dose*. In fact, a unique advantage of certain embodiments of a tablet within the scope of claim 53 allows splitting of the dose without *any* variation in the doses contained in each tablet half ("tablette").

A tablet of claims 54-56, having a height greater than its width (i.e., a taller-than-wide tablet), also provides its advantage of accurate dose splitting due to the unique tablet configuration. The claimed taller-than-wide tablet contains an inactive segment between two active segments wherein the inactive segment advantageously serves as a breaking segment, whereby the dose can be divided without significant variation in the resultant partial doses because there is no breakage or other detrimental effect occurring to the active segments.

Therefore, Lieberman does not simply fail "to teach how deep of a score a tablet should have," as re-asserted in the instant Office Action; rather, Lieberman fails to describe a tablet having an inactive outer segment as expressly recited in claim 53, *and* Lieberman further fails to describe a taller-than-wide tablet of claims 54-56. Lieberman is limited in its teaching to a conventional (wider-than-tall), three-layered tablet having a thin, inactive separating layer disposed between two incompatible active layers. The inactive layer of Lieberman cannot serve as a breaking segment that provides accurate and precise dose splitting. Lieberman never hints of providing an advantage of tablet splitting without variation in dosage. Therefore, Lieberman fails to teach or suggest anything close to the claimed tablets.

In addition, there is no teaching or suggestion in Lieberman to modify the three-layer tablet of Lieberman to provide a tablet of claim 53, having an active layer and an inactive outer layer serving as a breaking segment. Nor is there any teaching or suggestion in Lieberman to modify the conventional wider-than-tall tablet to provide a taller-than-wide tablet having an inactive middle segment that serves as a breaking segment. Both of these structural aspects of the subject invention are unique to the claimed invention and are unobvious in view of the prior art.

The Office Action then brings in the Ullman reference as teaching a multi-fractionable unitary tablet structure. However, Ullman does not disclose a tablet having more than one layer – only a single-layer tablet, compressed from a single homogeneous composition. Applicants respectfully traverse the applicability of the single-layer tablet of Ullman to the multi-layered tablet of Lieberman, or the claimed invention. The scoring aspect of the tablets described in Ullman, cannot cure the defects of Lieberman because Lieberman is defective in its teaching vis-a-vis the subject invention in ways that are not related to scoring of the tablets, as explained above.

The Office Action asserts that, a person of ordinary skill would be motivated to utilize the superior score of Ullman with the layered tablet of Lieberman, and that there would have been a reasonable expectation of success by combining Ullman with Lieberman. However, in view of the limitations of both of the cited references, there would have been no success at arriving at the claimed invention. Providing a score of Ullman in a layered tablet of Lieberman would result in a scored, conventional (wider-than-tall), three-layered tablet. This combined Lieberman/Ullman tablet could never be broken without affecting the partial doses in the divided tablet portions because the conventional wider-than-tall tablet breaks through all layers simultaneously, and cannot be readily split through an inactive layer only, as is achieved by the claimed tablets.

The distinction between breaking a taller-than-wide layered tablet of the subject invention and breaking a conventional wider-than-tall layered tablet (e.g., as described in Lieberman), is illustrated below:

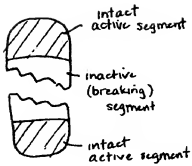

FIG. A. Breaking of a taller-than-wide layered tablet configuration

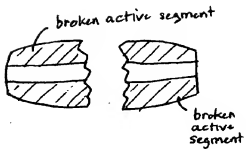

FIG.B. Breaking of a wider-than-tall layered tablet configuration

FIG. A illustrates the advantageous "breaking layer" formed by a middle inactive segment in a taller-than-wide tablet, providing breakage through the inactive layer and resulting in the active segments remaining intact – even if the break is not exactly through the midline. By contrast, a wider-than-tall layered tablet cannot provide the same advantageous break.

As shown in FIG. B, above, breaking a wider-than-tall tablet across its short axis results in breaking through all layers of the tablet. It is well known that the broken faces or edges of a tablet may chip or crumble, thus inevitably resulting in loss of mass, and therefore loss of some of the active ingredient

The Office Action further asserts that it would have been obvious to replace the incompatible drugs with compatible drugs in a three-layered tablet of Lieberman. However, such assertion fails because only in hindsight, using the benefit of applicants' disclosure, would one arrive at this substitution. There is no motivation to include an inert barrier layer between two compatible drugs. Moreover, hindsight reconstruction of the invention, using the disclosure of the subject application, is impermissible and cannot be used to support an obviousness rejection.

An inert barrier layer between two compatible drugs in a conventional tablet is superfluous, and persons of ordinary skill in the tablet manufacturing arts would not be motivated to include an inert layer where it was not absolutely necessary because minimizing time, costs, and tablet size are factors that would motivate a person to not include the inert layer between compatible drug layers. Accordingly, applicants believe the prior art teaches away from a tablet having an inert barrier layer between two compatible drug layers. Additionally, the Office Action submits that the effective height of the inner segment is simply a result of size optimization. However, optimizing the size of the tablet is different than optimizing the size of the inner segment. There

is nothing in the prior art that teaches or suggests modification of one segment and not the other two segments in a three-segment tablet. Applicants respectfully submit that it would be well recognized in the art that increasing the size of a whole tablet described in the prior art to provide an effective height for the inner segment consistent with the claimed invention would result in a tablet too large to swallow and, therefore, inoperable. Because the prior art does not teach or suggest size modification of only a single segment, there is no basis to make such assertion against the claimed invention. In view of the above, reconsideration and withdrawal of the rejection under 35 USC §103(a) is respectfully urged.

IV. Obviousness-type Double Patenting Rejection

Claims 53-71 and 76-80 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of co-pending application Serial No. 10/598,344 in view of Lieberman and Ullman. Because the instant claims have been amended, and the claims of either the instant application or the cited '344 application have not yet been allowed, applicants respectfully submit that the issue of obviousness-type double patenting, and the submission of a terminal disclaimer to overcome the obviousness-type double patenting rejection, will be considered upon indication of allowability for the claims.

In view of the above amendments to the claims and the accompanying Remarks, applicants believe that the pending claims, as amended, are in condition for allowance and respectfully request issuance of the Notice of Allowance.

Applicants invite the Examiner to contact the undersigned at the address and/or phone number provided below if clarification or additional information is needed on any of these matters.

Respectfully submitted,

Dated: August 30, 2010

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